

PCVI42

ASSESSING THE QUALITY OF QUALITY OF LIFE MEASURES IN HEART FAILURE: A COMPARISON OF AVAILABLE INSTRUMENTSHerdman M¹, Garin O¹, Vilagut G¹, Ribera A², Permanyer-Miralda G³, Ferrer M⁴, Rajmil L⁴, Valderas JM⁵, Alonso J¹¹CIBER en Epidemiología y Salud Pública (CIBERESP), Barcelona, Cataluña, Spain, ²Hospital Vall d'Hebrón, Barcelona, Cataluña, Spain, ³Institut Municipal d'Investigació Mèdica, Barcelona, Cataluña, Spain, ⁴Catalan Agency for Health Technology Assessment and Research, Barcelona, Cataluña, Spain, ⁵University of Manchester, Manchester, UK

OBJECTIVES: To evaluate and compare the performance of available disease-specific health-related quality of life (HRQL) instruments for use in heart failure. **METHODS:** A systematic review identified 5 disease-specific HRQL questionnaires for use in heart failure (Minnesota Living with Heart Failure questionnaire [MLHFQ], Chronic Heart Failure questionnaire [CHFQ], Kansas City Cardiomyopathy questionnaire [KCCQ], Left Ventricular Disease Questionnaire [LVDQ], and the Quality of Life in Severe Heart Failure Questionnaire [QLSHFQ]). The 5 questionnaires were evaluated using EMPRO (Evaluating Measures of Patient Reported Outcomes), a tool for the standardized assessment of the psychometric properties and usability of patient reported outcome measures. Groups of four expert appraisers evaluated 8 attributes for each instrument and gave an overall recommendation after a consensus procedure. Scores ranged from 0 (worst possible score) to 100 (best possible score). Inter-rater agreement (intra-class correlation coefficient – ICC) was analyzed and median scores and ranges for all EMPRO attributes were calculated. An overall recommendation was provided (highly recommended, recommended with provisos, not recommended, unsure). **RESULTS:** Inter-rater agreement for EMPRO was generally acceptable (ICC of 0.48 – 0.93 for individual attributes). Median overall EMPRO ratings and attribute score ranges were: MLHFQ (59.8, 33.3–69.4), CHFQ (54.9, 38.1–72.2), KCCQ (47.2, 38.1–100), LVDQ (47.7, 11.1–76.7), and QLSHFQ (7.7, 5.6–26.6). The highest scores for all instruments except the QLSHFQ were on responsiveness (median scores from 5.6 to 100). Three of the questionnaires (MLHFQ, CHFQ, KCCQ) were recommended with provisos; the LVDQ and QLSHFQ were not recommended. **CONCLUSIONS:** Of the 5 instruments evaluated, 2 (MLHFQ, CHFQ) scored well on EMPRO and were recommended, whilst the others may be limited to use in particular types of study or require further investigation. This type of assessment can provide useful information for questionnaire selection. Funding: This work was supported by grants from Instituto de Salud Carlos III FEDER, (PI08/90724).

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EXPLORING PATIENTS' SATISFACTION WITH ANTICOAGULANT TREATMENT BY APPLYING STRUCTURAL EQUATION MODELS TO THE PERCEPTION OF ANTICOAGULANT TREATMENT QUESTIONNAIRE (PACT-Q)Regnault A¹, Gilet H¹, Carita P², Arnould B³¹Mapi Values France, Lyon, France, ²Sanofi Aventis R&D, Paris, France, ³Mapi Values, Lyon, France

OBJECTIVES: To explore the process of patients' satisfaction with anticoagulant treatment using Structural Equation Modeling (SEM). **METHODS:** The Perception of AntiCoagulant Treatment Questionnaire (PACT-Q) includes 2 modules: a 7-item module assessing patient expectations of anticoagulant treatment and a 20-item module assessing treatment convenience and patient satisfaction. It was completed by deep venous thrombosis, atrial fibrillation and pulmonary embolism patients in 3 clinical trials assessing anticoagulant treatments. The first module was administered at baseline (BL) and the second after 3 (M3) and 6 months (M6). SEM was applied to pooled data from the three trials. SEM specifications were supported by the questionnaire conceptual model, satisfaction theory and the scoring rules of the instrument. The goodness of fit of the models was assessed using a set of commonly used fit indices including the Root Mean Square of Approximation (RMSEA). Association between latent variables was assessed using Standardized Path Coefficients (SPC). **RESULTS:** A total of 986 patients had fully completed PACT-Q at BL, M3 and M6. PACT-Q items allowed good measurement of Convenience (RMSEA = 0.054) and Satisfaction (RMSEA = 0.028) at M3. The 7 expectation items were kept independent. An overall model involving two expectation items (expectations of symptom relief, worries about making mistakes) and both Satisfaction and Convenience at M3 and M6 was estimated (RMSEA = 0.032). In this final model, Convenience had a stronger impact on Satisfaction at M3 than at M6 (respective SPC: 0.57 vs 0.48). Convenience at M6 was very strongly related with Convenience at M3 (SPC: 0.80) while the relationship between Satisfaction at M3 and M6 was weaker (SPC: 0.52). **CONCLUSIONS:** The application of SEM to the PACT-Q data allowed the prominent role of patients' expectations and perception of treatment convenience in the process of anticoagulant treatment satisfaction to be highlighted. Convenience was also shown to be more stable over time than satisfaction.

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HEALTH-RELATED QUALITY OF LIFE AND RESOURCE USE IN PATIENTS WITH METABOLIC SYNDROME: A COMPARISON OF THE UNITED STATES, EUROPE, AND JAPANWagner S¹, Fukuda T², Nagae T³, Gupta S¹, DiBonaventura M¹, Stankus AP¹¹Consumer Health Sciences International, Princeton, NJ, USA, ²University of Tokyo, Bunkyo, Tokyo, Japan, ³York Pharma KK, Tokyo, Japan

OBJECTIVES: To compare health-related quality-of-life (HRQoL) and resource use in patients with metabolic syndrome across three geographies. **METHODS:** Data used from the 2008 National Health and Wellness Survey (NHWS), an annual internet

survey of adults in the US, EU (Germany, Spain, Italy, UK, and France), and Japan (JPN). Metabolic syndrome was defined as having at least three of: diabetes, BMI ≥ 30 , high cholesterol, or hypertension. Resource use included emergency room (ER) visits, hospitalizations, and visits to traditional health care providers. Linear regression was used to determine the effects of geography on the physical component summary score (PCS) and mental component summary score (MCS) of the SF-12, and Poisson regression for resource use, controlling for age, gender and total number of comorbidities. **RESULTS:** Of the 11,131 patients with metabolic syndrome 2,503, 185 and 8,443 were from EU, JPN, and US, respectively. All prevalence numbers were significantly different from one another ($p < 0.05$). Mean MCS scores were 45.86, 45.84, and 47.39 for EU, JPN and US, respectively, with a significant difference between EU and US ($p < 0.05$). The PCS score for JPN (44.86) was significantly higher than both US (38.76) and EU (38.41) PCS scores ($p < 0.05$). After controlling for confounders, JPN MCS scores were 2.87 points lower than the US ($p < 0.05$), while EU scores were 2.09 points lower ($p < 0.05$). JPN PCS scores were 4.92 points higher ($p < 0.05$), and EU scores were 1.22 points lower than the US ($p < 0.05$). The regression results for resource use showed JPN with fewer ER visits than US, and both JPN and EU with more hospitalizations, and more provider visits ($p < 0.05$). **CONCLUSIONS:** There are significant differences in prevalence and possibly awareness of metabolic syndrome across the three regions. Also, significant differences were seen in both HRQoL and resource use. Further research is needed to describe the burden of metabolic syndrome globally.

PCVI45

IMPACT OF HOSPITALIZATION ON HEALTH-RELATED QUALITY OF LIFE IN ATRIAL FIBRILLATION PATIENTSReynolds MR¹, Hui G², Zimetbaum P¹¹Beth Israel Deaconess Medical Center, Boston, MA, USA, ²Harvard Clinical Research Institute, Boston, MA, USA

OBJECTIVES: Hospitalization is recognized as an important endpoint in atrial fibrillation (AF) clinical trials. The association between hospitalization and reduced health-related quality of life (HRQoL) has not been studied. Therefore, a large AF registry was used to characterize the impact of hospitalization on HRQoL. **METHODS:** The FRACTAL study was an observational registry of patients enrolled in the United States and Canada with new-onset AF. HRQoL was assessed with the SF-12 and the AF Symptom Checklist at baseline, 3, 6, and 12, 24 and 30 months. Mixed linear regression models were fitted to estimate the impact of hospitalization on HRQoL summary scores (physical and mental component scores of SF-12, symptom frequency and severity, and utilities from the SF-12), adjusting for demographic and clinical variables known to influence HRQoL in this population. **RESULTS:** Of 933 subjects who completed HRQoL questionnaires and were not hospitalized during the baseline study visit, 303 (32%) were hospitalized a total of 490 times during an average of 2.0 years of follow-up. The majority (64%) of these admissions were for cardiovascular causes. The adjusted effect of any hospital admission (vs. none) on symptom frequency and severity scores over time was +1.3 and +1.1 points, respectively ($p < 0.01$ for both), with higher scores indicating greater symptom burden. The adjusted effect of any admission on the SF-12 physical score was –2.7 points ($p < 0.0001$) and a decrement on utility of 0.03 ($p < 0.0001$). In contrast, hospitalization had little effect on longitudinal SF-12 mental scores (–0.7 points, $p = 0.15$). **CONCLUSIONS:** In a real life long term AF registry, hospitalizations during follow-up were associated with significant increases in AF symptoms and decrements in generic physical HRQoL and utilities. Based on these results which may be limited by the study design, interventions that reduce hospital admissions in AF patients would be expected to improve or preserve HRQoL.

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HAS THE TYPE OF ATRIAL FIBRILLATION DIFFERENT IMPACT ON HRQoL?Arribas F¹, Ormaetxe JM², Peinado R³, Fernandez C⁴, Ramirez P⁴, Badia X⁵¹Hospital 12 de Octubre, Madrid, Spain, ²Hospital de Basurto, Bilbao, Spain, ³Hospital La Paz, Madrid, Spain, ⁴MEDA Pharma, Madrid, Spain, ⁵IMS Health, Barcelona, Spain

OBJECTIVES: To assess whether the type of atrial fibrillation (AF) could have a different impact on patients' HRQoL. **METHODS:** An observational, prospective, multicentre study among 29 cardiologists specialized in arrhythmia, in the context of usual clinical practice was carried out to validate the AF-QoL questionnaire. AF patients (paroxysmal, persistent or permanent) were included. Variables recorded were age, NYHA scale, symptoms (number and frequency), emergency visits and AF-QoL score. **RESULTS:** A total of 341 AF patients were included (43% with persistent AF, 37% with paroxysmal AF and 20% with permanent AF). Paroxysmal AF patients were the youngest, with a mean age (SD) of 57(13) years, and reported better physical state, according to NYHA scale (67%, class I). Palpitations were the most prevalent symptom in paroxysmal AF patients (91%); dyspnea was the most prevalent symptom in persistent (70%) and permanent AF (77%). Paroxysmal AF patients reported the greatest number (4.5(2.5)) and frequency of symptoms (30% reported weekly symptoms), as well as the major number of emergency visits (2.2(1.7)) ($p < 0.05$). Permanent AF patients showed better HRQoL in the psychological dimension of AF-QoL (47(28) points vs 38(26) and 37(26) in paroxysmal and persistent AF, respectively) ($p = 0.03$). The rest of AF-QoL domains were similar between AF patients. The presence of symptoms was associated to a decrease in HRQoL in all AF patients, especially palpitations in paroxysmal AF patients and palpitations, dyspnea and chest pain in permanent AF. Moreover, the more frequent the symptoms, the lower the AF-QoL score ($p < 0.05$). A correlation was observed between the increase of emergency visits

and the decrease in AF-QoL score, particularly in paroxysmal and persistent AF patients. **CONCLUSIONS:** The main impact on HRQoL in AF patients was not conditioned by the type of AF, but the clinical presentation, especially number and frequency of symptoms.

PCV147

EXPERIENCE WITH UPPER GASTROINTESTINAL SYMPTOMS IN PATIENTS WITH CARDIOVASCULAR RISK TREATED WITH LOW-DOSE ACETYLSALICYLIC ACID

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OBJECTIVES: To describe the experience with upper gastrointestinal (GI) symptoms, the impact of symptoms on daily life, and nonadherence and discontinuation of low-dose acetylsalicylic acid (ASA) treatment in patients with cardiovascular (CV) risk. **METHODS:** Twenty-two patients from the US were selected to undergo face-to-face, 1-hour qualitative interviews following a multicentre 3-month observational study of patients ≥ 18 years at risk of or with CV disease, about to begin or previously prescribed daily low-dose ASA (75–325 mg) within 5 years (ClinicalTrials.gov identifier: NCT00681759; AstraZeneca study code: D961FC00004). Interviewee-selection was based on low-dose ASA history, CV risk, GI medication use, and the occurrence of ≥ 1 upper GI event during the study period. Interviews were semi-structured and were audio-recorded and transcribed for analysis. **RESULTS:** 16 interviews were evaluable (mean age 44.7 years; 68.8% women); 6 patients were excluded following technical failure or violation of inclusion/exclusion criteria. Commonly reported upper GI symptoms were: burning feeling behind the breastbone ($n = 9$); burning feeling in the upper stomach ($n = 4$); acid taste in the mouth ($n = 4$); regurgitation ($n = 4$). Upper GI symptoms negatively impacted aspects of patients' lives, including: food intake ($n = 12$); sleep quality ($n = 6$); emotions ($n = 5$). Most patients reported occasional over-the-counter medication use; many altered their diet to manage upper GI symptoms. Overall, five patients reported treatment nonadherence. Upper GI symptoms caused nonadherence in 3 patients; 2 missed doses when GI symptoms were severe, despite being aware of low-dose ASA benefits. Patients who understand the purpose of their low-dose ASA prescription could articulate the importance of adherence and the intention to continue therapy. **CONCLUSIONS:** Patients who understand the purpose of low-dose ASA treatment are more likely to adhere to therapy, although doses may be intentionally missed due to upper GI symptoms.

PCV148

HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH HYPERCHOLESTEROLEMIA

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OBJECTIVES: In patients with chronic diseases such as hypercholesterolemia, health-related quality of life (HRQoL) is an important outcome. The objective of the present study was to determine factors associated with an impaired HRQoL after 12 months. **METHODS:** Patients with hypercholesterolemia were prospectively included in the ORBITAL (Open-label primary care study: Rosuvastatin-Based compliance Initiatives linked To Achievement of LDL goals) Study. Inclusion criteria were hypercholesterolemia with an indication for statin therapy according to the European Guidelines. Follow-up was 12 months. A total of 1961 primary care practices in Germany participated. HRQoL was assessed with the Short Form (SF)-12 health status instrument. **RESULTS:** Of the 7640 patients included, 47% were high-risk patients in the primary prevention of coronary heart disease, 42% were patients with coronary heart disease, and 11% did not have a priori risk stratification. Physical SF-12 summary scores were inversely associated with risk stratum, however, there was no such association between mental SF-12 summary scores and risk stratum. An impaired physical SF-12 score was associated with increased age, lower educational level, higher body mass index, smoking, existing coronary heart disease, a history of stroke, or a clinical event during follow-up. An impaired mental SF-12 score was associated with younger age, hypertension, or a clinical event during follow-up. **CONCLUSIONS:** HRQoL in patients with hypercholesterolemia is associated with socioeconomic factors, lifestyle, and clinical events. Effective prevention is thus not only essential for clinical outcome but also for the maintenance of HRQoL in patients with hypercholesterolemia. ClinicalTrials.gov Identifier: NCT00379249.

PCV149

ASSESSMENT OF QUALITY OF LIFE AMONG PATIENTS WITH HYPERTENSION AND DIABETES TYPE 2

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OBJECTIVES: The assessment of quality of life among ambulatory patients with hypertension (HTN), diabetes type 2 (DM2) or coexisting HTN and DM2 (HTN+DM2). **METHODS:** Patients of 4 ambulatory care setting in Cracow (Poland) with HTN, DM2 or HTN+DM2 were included. Polish versions of SF-36v2 and EQ-5D were used with the supplementary questions about age, gender, education, body mass, place of residence. Student's t-test was used to compare the differences between

paired groups. **RESULTS:** A total of 135 patients were included (68 with HTN, 22 with DM2, 45 with HTN+DM2); 57.8% of patients were women. 31.11% of patients with HTN+DM2, 36.77% of patients with HTN and 72.73% of patients with DM2 assessed their health status as well, none indicated the answer excellent or very good. Usually women indicated their QOL lower than men (HTN: PF, RP, PCS $p < 0.05$; HTN+DM2: PF, PB $p < 0.05$). PCS was rated lower or similar to MCS; HTN: PCS 39.30 ± 7.88 , MCS 40.45 ± 10.96 , DM2: PCS 42.77 ± 8.22 , MCS 42.23 ± 9.86 ; HTN+DM2: PCS 38.89 ± 9.05 , MCS 42.66 ± 10.66 . Due to EQ-5D 80% of patients had no problems with self care and 60% – with usual activities. Over 85% of patients had moderate or extreme pain or discomfort, more than 70% of patients felt moderately or extremely anxious or depressed. About 75% of patients with HTN and HTN+DM2 confirmed problems with walking around. On VAS scale, patients with HTN, DM2 and HTN+DM2 assessed their health state accordingly: 54.87 \pm 15.70, 59.14 \pm 21.06, 55.56 \pm 14.50, with no statistically significant differences between diseases and sexes. **CONCLUSIONS:** Patients with HTN and HTN+DM2 estimated their quality of life lower than patients with DM2.

PCV150

WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT IN PATIENTS WITH METABOLIC SYNDROME: A COMPARISON OF THE UNITED STATES, EUROPE, AND JAPAN

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OBJECTIVES: To investigate the differences in work productivity in patients with metabolic syndrome across three geographies. **METHODS:** Data from the 2008 National Health and Wellness Survey (NHWS), an annual internet survey of attitudes, behaviors, health status, and outcomes of adults in the US, EU (Germany, Spain, Italy, UK, and France), and Japan (JPN) were used for the analysis. Metabolic syndrome was defined as having at least three of the following: diabetes, BMI ≥ 30 , high cholesterol, or hypertension. Multiple regressions were used to determine the effect of geography on work productivity using the validated Work Productivity and Activity Impairment Questionnaire (WPAI) controlling for age, gender and total number of comorbidities. **RESULTS:** Of the 3,995 employed patients with metabolic syndrome in the analysis 881 (22.1%) were from Europe, 89 (2.2%) from JPN, and 3,025 (75.7%) from the US. EU patients (10.9%) had significantly higher levels of percent work missed in the past week due to health (absenteeism) than US (6.2%) and JPN (5.3%) patients. No significant differences amongst geographies were seen for percent impairment at work (presenteeism), however, EU patients had higher levels of percent overall work impairment compared to US patients ($p < 0.05$). For all metabolic patients ($n = 11,131$) activity impairment was significantly lower for JPN compared with US and EU ($p < 0.05$). After controlling for age, gender and number of comorbid conditions, the differences remained significant, with EU having higher absenteeism, overall work impairment, and activity impairment than the US, and JPN reporting less activity impairment than the US ($p < 0.05$). **CONCLUSIONS:** The effect of metabolic syndrome on work productivity differed significantly across the three geographies. Any combination of factors may explain these differences: awareness of the condition, treatment differences, cultural issues, and health systems, amongst other. Further research is needed to describe the impact metabolic syndrome may have globally.

CARDIOVASCULAR DISORDERS – Health Care Use & Policy Studies

PCV151

REVIEW OF STUDIES EVALUATING THE IMPACT OF POLICY-DRIVEN STATIN SWITCH PROGRAMS ON PATIENTS

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OBJECTIVES: Although cardiovascular disease remains a major cause of death and morbidity in western countries, statins are well recognized for their role in prevention. The on-going need to maintain cost-effective health care has led to greater use of policy-driven therapeutic substitution programs for statins; however the impact of these policies on patients is often under-reported. **METHODS:** A review of published literature describing the impact of policy-driven statin switch programs was conducted based on a MEDLINE search [using the following terms: Hydroxymethylglutaryl-CoA Reductase Inhibitors (MeSH), and statin, switch, interchange, substitute, substitution (all fields); limited to English language and 1989–2009] and a review of reference lists from selected papers. **RESULTS:** Twenty-three studies were identified. Seventeen studies evaluated the impact of a “switch down” to equal or less potent statins. 6 studies evaluated the impact of a “switch up” to more potent statins. Following introduction of “switch down” programs, 23–47% of patients were not eligible or willing to switch (7 studies), 17–38% of patients were switched to a non-equivalent (lower) dose of the new statin (3 studies), 4–11% of patients switched back to their original statin (5 studies), and switched patients were 19–33% less likely to be adherent to therapy compared to those with no switch. Persistence was significantly reduced among switch patients (2 studies). No significant trend in lipid levels was noted (12 studies) but loss of target levels was reported in 7–20% of patients (2 studies) and 3 studies reported an increase in vascular events or death after switching. Studies evaluating “switch up” programs consistently demonstrated improved reductions in lipid